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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/679,135 | 10/03/2003 | David J. Pinsky | 51917-CA-PCT-US/JPW/AJM/A | 2202 |

7590 06/26/2006

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| EXAMINER |
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PAK, JOHN D

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| ART UNIT | PAPER NUMBER |
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1616

DATE MAILED: 06/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/679,135

Applicant(s)

PINSKY ET AL.

Examiner

JOHN PAK

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 46, 49-62, 65, 89 and 90 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 46, 49-62, 65, 89 and 90 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10/03, 6/04, 9/04, 1/05, 4/06
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Claims 46, 49-62, 65 and 89-90 are pending in this application.

Applicant's election of Group XIV in the reply filed on 4/13/2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 46, 49-62, 65 and 89-90 will presently be examined to the extent that they read on the elected subject matter.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 46, 49-62, 65 and 89-90 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 46 has been amended as shown below:

46. (Currently Amended) A method for protectively treating a subject ~~at risk for~~ from an ischemic disorder as a result of organ transplantation which comprises administering to the subject via inhalation a gas comprising carbon monoxide in an amount and over a period of time sufficient to protectively treat the subject ~~for the ischemic disorder~~.

The Examiner's rejection of the claims is based on the following interpretation of the instant claims and originally filed disclosure:

| Subject | Scope of instant claims | Originally filed Disclosure |
|-----------------|---|--|
| Organ donor | Includes organ donor – see claim 90 | Includes organ donor – see spec. p. 134 |
| Organ recipient | Includes organ recipient because claim 90 shows that claim 46 encompasses more than just donor as the subject | Does not reasonably convey that the organ recipient is to be treated with CO also. See spec. p. 134, lines 4-34. |

Applicant's invention with respect to organ transplantation is somewhat different in that a subject undergoing other types of surgeries is one and the same, whereas in organ transplantation surgeries, there are two subjects, the organ donor and organ recipient. In the originally filed disclosure, applicant does not explicitly disclose treating the organ recipient with CO in an amount and over a period of time sufficient to protectively treat the organ recipient. However, in the amended claims, applicant is now clearly claiming treating the organ donor as well as the organ recipient by virtue of distinguishing claim language – independent claim 46 reads on “a subject ... as a result of organ transplantation” and dependent claim 90 requires the subject to be the organ donor. Hence, claim 46 must necessarily encompass organ recipient because claim 90 is *further* defining the subject matter of claim 46. If only the organ donor were encompassed by claim 46, claim 90 would be superfluous.

It is the Examiner's position that the originally filed disclosure reasonably conveyed treating only the organ donor. The Examiner bases this determination from applicant's failure to explicitly disclose treating the organ recipient with CO in an amount and over a period of time sufficient to protectively treat the organ recipient and applicant's exemplified characterization of ischemic disorders. On specification page 134, the following is disclosed about ischemic disorder and organ transplantation:

-134-

In the initial patent application, we revealed data indicating that endogenous production of carbon monoxide or administration of exogenous carbon monoxide is beneficial in protecting the brain against subsequent ischemic injury. As another example of
5 the use of carbon monoxide in treating an ischemic disorder, we have administered carbon monoxide to rats to test its effects on
improving lung preservation for transplantation (this is similar
to an ischemic disorder, because the donor lungs are removed from
a recipient; during the period in which the lungs are preserved
10 and transferred from donor to recipient, there is an interruption
in blood flow).

On specification page 135, the donor mammal is treated with CO:

Administration of Carbon Monoxide:

At the indicated time before surgery (4, 8, or 12 hours), rats were placed in a bell jar, and carbon monoxide was administered
30 at various concentrations (0.01%, 0.03%, or 0.1%), with the remainder of the gas mixture consisting of room air. (The gas was passed through a jar of water prior to administration, in order to humidify it for animal comfort). At the indicated times following initiation of exposure, rats were anesthetized and
35 lungs harvested as described above. These donor lungs were used
in subsequent lung transplant experiments.

Applicant thus conveyed in the specification that treating an ischemic disorder in organ transplantation surgery means improving organ preservation for transplantation. The protocol provided on specification page 135 adds to this understanding.

Therefore, the instant claims, which read on treating both the organ donor and the organ recipient, fails to find adequate descriptive support from the originally filed disclosure. The claims are thereby rejected.

The following references are cited to further show the state of the art:
US 2006/0003922, 2004/0131703, 2002/0155166.

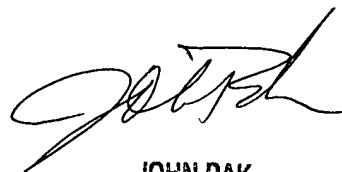
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JOHN PAK whose telephone number is **(571)272-0620**. The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Johann Richter, can be reached on **(571)272-0646**.

The fax phone number for the organization where this application or proceeding is assigned is **(571)273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



JOHN PAK
PRIMARY EXAMINER
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